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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/615,158 | 07/07/2003 | Jeffrey P. Gilbard | AVR-005 | 8240 |
| 959 | 7590 | 02/07/2008 | EXAMINER | |
| LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127 | | | FAY, ZOHREH A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1612 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/07/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/615,158 | GILBARD, JEFFREY P. |
| | Examiner | Art Unit |
| | Zohreh A. Fay | 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 August 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 and 8-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 and 8-42 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

Claims 1-6 and 8-42 are presented for examination.

The amendments and remarks filed on August 22, 2007 have been received and entered.

Claims 1-6 and 8-42 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ueno (US 6,566,398) in view of Yano et al. (submitted by the applicant), Troyer et al. (US 6,506,412) and Schneider et al. (US 6,353,022) for the reasons set forth on pages 2-4 of the office action of July 26, 2006 and page 2 of the office action of May 22, 2007.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the high concentrations of EPA and DHA. The allegation is not well taken, considering that Troyer et al. teach the combination of omega-3 fatty acids, omega-6 fatty acids and GLA at least 94 mg. Furthermore, the determination of optimum proportions or amounts are considered to be within the skill of the art in the absence of evidence to the contrary. The combination of relied upon references clearly teach the combination of DHA and EPA for the treatment of dry eye. The references also make clear that Vitamin B12 has been previously used as an antioxidant in compositions used for the treatment of dry eye. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-6 and 8-42 are properly rejected under 35 U.S.C. 103.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Zohreh Fay